

REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed July 8, 2005. Claims 1, 5-8, 10-11, 14-29, 31-45, and 50 are pending. Claims 1, 25, 26, 27, 34, and 42 are amended to correct minor informalities. No new matter is introduced by these amendments. Applicants respectfully request reconsideration for the following reasons.

Statement of Substance of Interview

On November 4, 2005, an interview was conducted at the United States Patent and Trademark Office between Examiner Saucier and Preben Christensen, Heidi Petersen, Stanislaus Aksman, and Jeff B. Vockrodt. The Office Action utilized Takizawa, see below, as the primary reference in an obviousness rejection of the pending claims. During the interview, Takizawa was discussed and reasons were given as to why the pending claims are patentable over Takizawa. It was recognized during the interview that Takizawa, page 179 teaches first measuring sperm viability and then measuring sperm count, since the immunocheck beads are added after measuring viability. Accordingly, Applicants submitted that Takizawa does not measure sperm viability and sperm count in the same determination step.

Applicants also presented arguments as to why certain dependent claim limitations are not critical to the patentability of the invention defined by the pending independent claim. The specification, at page 5, lines 22-31, discusses a computer-assisted microscopy method utilizing a cuvette having an exactly defined volume showing that beads are not necessary to practice the independent claim when such systems are used. Also discussed during the interview were the Partec PAS and Guava EasyCyte flow cytometers, which are capable of operating without the use of beads as an internal volume control. See Appendices A and B.

Indefiniteness -- 35 U.S.C. § 112, Second Paragraph

The Office Action rejects claims 1, 5-8, 10, 11, 14-29, 31-45, and 50 under 35 U.S.C. §112, second paragraph, as being indefinite because the independent claim included an expression in parenthesis. Specifically, the Office Action suggested that it is unclear whether the claim is meant to be further limited by this expression. Applicants submit that claim 1 without

the present amendment was in full compliance with the statutory definiteness requirement of 35 U.S.C. § 112, second paragraph. Nevertheless, claim 1 has been amended to remove the expression in parenthesis. This amendment is merely cosmetic and in no way changes the scope of the claims. Accordingly, the rejection of claims 1, 5-8, 10, 11, 14-29, 31-45, and 50 under 35 U.S.C. § 112, second paragraph, as being indefinite must be withdrawn.

Obviousness -- 35 U.S.C. § 103(a)

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. § 2143.03. In order to establish obviousness, "the prior art as a whole must 'suggest the desirability' of the combination." In re Fulton, 73 USPQ2d 1141, 1145 (Fed. Cir. 2004) (citing In re Beattie, 974 F.2d 1309, 1311 (Fed. Cir. 1992); Winner Int'l Royalty Corp. v. Wang, 53 USPQ2d 1580 (Fed. Cir. 2000)).

The Office Action rejects claims 1, 5-8, 10, 11, 14-24, 28, 29, 31, 37, 44, 45, and 50 under 35 U.S.C. § 103(a) as obvious over Takizawa et al., "Flow Cytometric Analysis for the Evaluation of the Rat Sperm Viability and Number in the Male Reproductive Toxicity Studies," Cong. Anom. 35:177-187 1995 ("Takizawa") in view of Live/Dead Sperm Viability Kit, L-7011, Molecular Probes Product Information 08/11/99 ("Viability Kit") or Garner et al., "Viability Assessment of Mammalian Sperm Using SYBR-14 and Propidium Iodide," Biology of Reproduction 53, 276-284 (1995) ("Garner").

Takizawa

The Office Action asserts that Takizawa teaches and suggests measuring viability and absolute concentration of sperm in "one pass on the FACScan." Office Action, pages 2-3. Applicants disagree with this characterization and submit that Takizawa in fact suggests, on pages 179, last paragraph and page 186, second paragraph, measuring viability and absolute concentration of sperm cells sequentially in separate measurements. Accordingly, Takizawa does not suggest "determination of the absolute concentration of sperm cells and of the

proportion of live sperm cells in the semen sample . . . simultaneously in the same determination step” as required by the claims.

Takizawa teaches that viability can be measured using a FACScan Flow Cytometer. Specifically, after staining with PI and then using the FACScan Flow Cytometer, Takizawa measures “the rates of viable and dead spermatozoa.” Takizawa, page 179, first paragraph. Takizawa uses immunocheck beads as an internal standard to measure sperm concentration. At page 179, last paragraph, Takizawa states “To each sample (1ml) after measuring for sperm viability, and 100µl of Immuno-check was added and mixed.” Therefore, Takizawa measures sperm count after measuring sperm viability. If sperm viability and sperm count are measured simultaneously, the beads of the internal volume standard would clearly be separated from the cells in a dot-plot. See, for instance, the beads of the internal volume standard used in the present invention which are clearly present and labeled “e” in the dot plot of Fig. 1 of this application. Takizawa’s Fig. 1A is a dot plot for viability assessment that does not indicate the presence of beads, which proves that Takizawa assesses viability at a different time than sperm count. Compare Fig. 1a of Takizawa with Fig. 1 of Applicants’ specification.

The Office Action points to page 186,¹ second paragraph of Takizawa, which states the following:

When we measured sperm number and viability simultaneously, sperm viability had decreased by 5 minutes after the addition of Immuno-Check standard beads as an internal volume standard (data not shown). As Immuno-check had a slight effect on sperm viability, we suggest that sperm viabilities should be analyzed first and followed by determination of sperm number.

Takizawa does not specify what is meant by “simultaneously” or how simultaneous measurement is conducted, but does state that viability should be measured in the absence of immunocheck beads (i.e., measure viability and then sperm count), since immunocheck beads affect the measurement of viability. Nothing in Takizawa suggests that one should measure viability and concentration in the same determination step. Indeed, Takizawa teaches away from

¹ Actually, the Office Action refers to page 180, but it is clear from the context of the citation and the small page numbering that page 186 of Takizawa was intended.

the Applicants' claimed invention by stating that viability should be measured first and then sperm number.

Live/Dead Sperm Viability Kit and Garner et al.

The Live/Dead Sperm Viability Kit and Garner are both directed to the distinction between live and dead sperm cells in a semen sample. Neither reference discusses measuring cell concentration. Although both documents teach the use of SYBR-14 and PI for staining all cells and all dead cells, respectively, they do not propose or recognize that it is possible with these two coloring agents and a cytometer to determine in a sample the absolute cell concentration and the proportion of live sperm cells simultaneously in the same determination step.

The Applicants' claimed invention is non-obvious in that none of the cited references taken alone or in combination teaches or suggests the claimed invention as a whole.

Specifically, Takizawa fails to teach or suggest:

determining the absolute concentration of the sperm cells and the proportion of live sperm cells by means of a detection means responsive to the selective staining, wherein the determination of the absolute concentration of sperm cells and of the proportion of live sperm cells in the semen sample are performed simultaneously in the same determination step.

As discussed above, Takizawa nowhere states that a simultaneous determination is desirable, and indeed teaches determination of viability before sperm count to avoid the impact of immunocheck beads. The Live-Dead Sperm Viability Kit and Garner do not mention measurement of absolute sperm concentration and thus fail to cure the deficiencies of Takizawa. The cited references taken as a whole fail to teach or suggest the claimed invention. Accordingly, the rejection of claim 1, and claims 5-8, 10, 11, 14-24, 28, 29, 31, 37, 44, 45, and 50 which depend from claim 1, as being obvious in view of Takizawa, Live/Dead Sperm Viability Kit, and Garner is improper and must be withdrawn.

Declaration Evidence

The Office Action alleges that the evidence in the declaration showing unexpected results is not commensurate in scope with the claims "because the inclusion of the fluorescent standardization particles is missing from the claimed method." The specification discloses methods of measuring sperm concentration without the use of an internal volume standard. For

example, the specification, at page 5, lines 22-31, discusses a computer-assisted microscopy method utilizing a cuvette having an exactly defined volume showing that the beads are not necessary to practice the independent claim. Therefore, the inclusion of fluorescent standardization particles is not necessary to practice the invention of the pending independent claim.

Dependent claims

The Office Action rejects claims 25-27 under 35 U.S.C. § 103(a) as obvious over Takizawa in view of Viability Kit or Garner in combination with EP 0586183. However, EP 05869183 fails to cure the deficiencies of Takizawa, Viability Kit, and Garner with respect to claim 1, which is allowable as discussed above. Claims 25-27 are allowable as they depend from and incorporate the limitations of allowable claim 1.

The Office Action rejects claims 32-34, 39, 41, 42, and 43 under 35 U.S.C. § 103(a) as obvious over Takizawa in view of Viability Kit or Garner, further in view of Sexton, Januskauskas, Belorkar, or Bostoft. However, neither Sexton, Januskauskas, Belorkar, nor Bostoft cures the deficiencies of Takizawa, Viability Kit, and Garner with respect to claim 1, which is allowable as discussed above. Claims 25-27 are allowable as they depend from and incorporate the limitations of allowable claim 1.


The Office Action rejects claims 35 and 40 under 35 U.S.C. § 103(a) as obvious over Takizawa in view of Viability Kit or Garner, further in view of Juonala or Viudes-De-Castro. However, neither Juonala or Viudes-De-Castro cures the deficiencies of Takizawa, Viability Kit, and Garner with respect to claim 1, which is allowable as discussed above. Claims 25-27 are allowable as they depend from and incorporate the limitations of allowable claim 1.

Conclusion

Applicants submit that this response addresses all of the issues raised in the Office Action and places the pending claims in condition for allowance. Should any issues remain to be discussed in this application, the undersigned may be reached by telephone. In the event any variance exists between the amount authorized to be charged to the Deposit Account and the Patent Office charges for reconsideration of this application, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

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